affiliation, mailing address, telephone number, email address);

• A letter of recommendation stating the qualifications of the candidate.

Nomination materials must be postmarked by December 30, 2011, and sent to: Kim Distel, Office of Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop D10, Atlanta, Georgia 30333, telephone (404) 639–2100.

Candidates invited to serve will be asked to submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the Centers for Disease Control and Prevention.'' This form allows CDC to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a lack of impartiality, as defined by Federal regulation. The form may be viewed and downloaded at *http://www.usoge.gov/forms/oge450_pdf/oge450_accessible.pdf.* This form should not be submitted as part of a nomination.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention, and the Agency for Toxic Substances and Disease Registry.

Dated: November 29, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–31429 Filed 12–6–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Planning, Research and Evaluation Advisory Committee on Head Start Research and Evaluation

AGENCY: Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of ACF. The meeting will be open to the public.

Name of Committee: Advisory Committee for Head Start Research and Evaluation.

General Function of Committee: The Advisory Committee for Head Start Research and Evaluation will provide feedback on the published final report for the Head Start Impact Study, offering interpretations of the findings, discussing implications for practice and policy, and providing recommendations on follow-up research, including additional analysis of the Head Start Impact Study data. The Committee will also be asked to provide recommendations to the Secretary regarding how to improve Head Start and other early childhood programs by enhancing the use of research-informed practices in early childhood. Finally, the Committee will be asked to provide recommendations on the overall Head Start research agenda, including—but not limited to—how the Head Start Impact Study fits within this agenda. The Committee will provide advice regarding future research efforts to inform HHS about how to guide the development and implementation of best practices in Head Start and other early childhood programs around the country.

DATES: The meeting will be held from 8:30 a.m. to 5 p.m. on January 18–19, 2012.

ADDRESSES: Washington Plaza Hotel, 10 Thomas Circle NW., Washington, DC 20005, *Phone:* (202) 842–1300.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Office of Planning, Research, and Evaluation, email *jennifer.brooks@acfhhs.gov* or call (202) 205–8212.

Agenda: The Committee will review draft recommendations developed by the subcommittees on the topics of quality teaching and learning; parent, family, and community engagement; the impact of Head Start and Early Head Start; health and mental health; and cultural and linguistic responsiveness.

Procedure: Interested persons may present data, information or views, in writing, on issues pending before the Committee. Written submissions may be made to Jennifer Brooks at *jennifer.brooks@acf.hhs.gov* on or before January 2, 2012. All written materials provided to the contact person will be shared with the Committee members.

ACF welcomes the attendance of the public at this advisory committee meeting and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Jennifer Brooks at least seven days in advance of the meeting. Information about the Committee and this meeting can be found at the Committee Web site, *http://www.acfhhs.gov/programs/opre/hs/advisory_com/.*

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 22, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–31196 Filed 12–6–11; 8:45 am]

BILLING CODE M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0608]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; MedWatch: The Food and Drug Administration Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by January 6, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, *Fax:* (202) 395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0291. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch: The FDA Medical Products Reporting Program—(OMB Control Number 0910–0291)—Extension

I. Background

To ensure the marketing of safe and effective products, postmarketing adverse outcomes and product problems must be reported for all FDA-regulated human health care products, including drugs, both prescription and over-the-counter (OTC); biologics; medical devices; dietary supplements and other special nutritional products (*e.g.,* infant formula and medical foods); and cosmetics. In addition, FDA has regulatory responsibility for tobacco products and an interest in receiving reports about adverse outcomes and product problems for these products.

Under sections 505, 512, 513, 515, 519 and 903 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355, 360b, 360c, 360e, 360i and 393) and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the FD&C Act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(2) of the FD&C Act, it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling. Under section 502(t)(2) of the FD&C Act, devices are considered to be misbranded if there has been a failure or refusal to give required notification or to furnish required material or information required under section 519. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, and 803 (21 CFR 310, 314, 600, and 803), specifically §§ 310.305, 314.80, 314.98, 600.80, 803.30, 803.50, 803.53, 803.56, and specified in sections 760 and 761 of the FD&C Act (21 U.S.C. 379aa and 379aa–1). Mandatory reporting of adverse reactions for human cells, tissues, and cellular and tissue-based products (HCT/Ps) has been codified in 21 CFR 1271.350.

FDA regulates the safety (*i.e.,* adulteration) of dietary supplements under section 402 of the FD&C Act (21 U.S.C. 342). Dietary supplements do not require premarket approval by FDA and the Agency bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Under section 761(b)(1) of the FD&C Act, a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States.

Mandatory reporting, since 1993, has been supplemented by voluntary reporting by health care professionals, their patients, and consumers via the MedWatch reporting process. To carry out its responsibilities, the Agency needs to be informed when an adverse event, product problem, error with use of a human medical product or evidence of therapeutic failure (inequivalence) is suspected or identified in clinical use. When FDA receives this information from either health care professionals or patients, the report becomes data that will be used to assess and evaluate the risk associated with the product, and then take whatever action is necessary to reduce, mitigate, or eliminate the public's exposure to the risk through regulatory and public health interventions.

To implement these provisions for reporting on human medical products during their postapproval and marketed lifetimes, two forms are available from the Agency. FDA Form 3500 is used for voluntary (*i.e.,* not mandated by law or regulation) reporting by health care professionals and the public. FDA Form 3500A is used for mandatory reporting (*i.e.,* required by law or regulation).

Respondents to this collection of information are health care professionals; medical care organizations and other user-facilities (*e.g.,* extended care facilities, ambulatory surgical centers); consumers; manufacturers of biological, dietary supplement, and drug products or medical devices; and importers.

II. Use of FDA Form 3500 (Voluntary Version)

The voluntary version of the form is used to submit all reports not mandated by Federal law or regulation. Individual health professionals are not required by law or regulation to submit reports to the Agency or the manufacturer, with the exception of certain adverse reactions following immunization with vaccines as mandated by the National Childhood Vaccine Injury Act of 1986. Those mandatory reports are not submitted to FDA on the 3500 or 3500A form but are submitted to the joint FDA/Centers for Disease Control and Prevention Vaccines Adverse Event Reporting System (VAERS) on the VAERS–1 form (see *http://vaers.hhs.gov/resources/vaers_form.pdf).*

Hospitals are not required by Federal law or regulation to submit reports associated with drug products, biological products, or special nutritional products. However, hospitals and other user facilities are required by Federal law to report medical device-related deaths and serious injuries.

Under Federal law and regulation (section 761(b)(1) of the FD&C Act), a dietary supplement manufacturer, packer, or distributor whose name appears on the label of a dietary supplement marketed in the United States is required to submit to FDA any serious adverse event report it receives regarding use of the dietary supplement in the United States. However, FDA bears the burden to gather and review evidence that a dietary supplement may be adulterated under section 402 of the FD&C Act after that product is marketed. Therefore, the Agency depends on the voluntary reporting by health professionals and especially by consumers of suspected serious adverse events and product quality problems associated with the use of dietary supplements.

III. Use of FDA Form 3500A (Mandatory Version)

A. Drug and Biologic Products

In sections 505(j) and 704 (21 U.S.C. 374) of the FD&C Act, Congress has required that important safety information relating to all human prescription drug products be made available to the FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the FD&C Act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the FD&C Act. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 parts 310 and 314 (drugs) and 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics. Mandatory reporting of adverse reactions for HCT/Ps has been codified in 21 CFR 1271.350.

The majority of the mandatory reports for drug products, which at inception of FDA Form 3500A's use were received by the Agency on the paper version of FDA Form 3500A (by mail or FAX), are now submitted and received by the Agency via an electronic submission route. In that case, the FDA Form 3500A is not used.

B. Medical Device Products

Section 519 of the FD&C Act requires manufacturers and importers of devices

intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services may by regulation reasonably require to assure that such devices are not adulterated or misbranded and to otherwise assure its safety and effectiveness. The Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the FD&C Act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. These statutory requirements regarding mandatory reporting have been codified by FDA under 21 CFR part 803, which mandates the use of FDA Form 3500A for reporting to FDA on medical devices. The Medical Device User Fee and Modernization Act of 2002, Public Law 107–250, signed into law October 26, 2002, amended section 519 of the FD&C Act. The amendment (section 303) required FDA to revise the MedWatch forms ''to facilitate the reporting of information * * * relating to reprocessed single-use devices, including the name of the reprocessor and whether the device has been reused.''

C. Nonprescription Drug Products and Dietary Supplements

Section 502(x) in the FD&C Act implements the requirements of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, which became law (Pub. L. 109–462) on December 22, 2006. These requirements apply to manufacturers, packers, and distributors of nonprescription (OTC) human drug products marketed without an approved application. The law requires reports of serious adverse events to be submitted to FDA by manufacturers of dietary supplements and nonprescription drugs.

IV. Proposed Modifications to Existing Forms 3500 and 3500A

A. General Changes

The proposed modifications to FDA Form 3500 and FDA Form 3500A reflect changes that will bring the form into conformation, since the previous authorization in 2008, with current regulations, rules, and guidances.

B. Changes Proposed for FDA Form 3500

No additional fields will be added and no fields deleted. There are no proposed formatting changes to the location or distribution of the fields. Modifications are proposed to several field labels and descriptions to better clarify for reporters the range of reportable products, including tobacco products and food (*e.g.,* food allergens causing allergic or anaphylaxis reactions). Descriptive text in the field labels and instructions were modified to permit a better understanding of data requested. For section E, field E4, the label ''Other'' will be renamed ''Unique Identifier #'' in anticipation of the use of this product information by the Agency for specific characterization and identification of the medical device. The form remains a one-sided, one-page form with instructions for use on the reverse side and a self-addressed, postage-paid return mailer.

C. Changes Proposed for FDA Form 3500A

Certain formatting changes are proposed to allow mandatory reporters to better utilize available space for data entry and facilitate specification of the device product's coding. In section D, field D2, it is proposed that the same field be used to request the procode (D2b) to correspond to the existing common device name (D2a). The D4 field currently named ''Other'' will be renamed ''Unique Identifier #.'' Section H, currently named ''Device Manufacturers Only'' will be renamed ''Manufacturers Only.'' Field H1 will have the ''Other'' checkbox removed and field H6, renamed ''Event Problem and Evaluation Codes,'' will have patient code and device code boxes added, as in the existing form's field F10. In section G, field G5, STN # will be relabeled BLA #. Given the need to contact mandatory reporters in a timely manner, the Agency proposes that a field be added to FDA Form 3500A to request an email address for the mandatory reporter, to supplement the phone number and mailing address currently included on the form. This change is proposed for fields E1 and G1.

V. Proposed Addition of Consumer Version of FDA Form 3500

FDA supports and encourages direct reporting to the Agency by consumers (patients and their caregivers) of suspected serious adverse outcomes and other product problems associated with human medical products (*http://www.fda.gov/Safety/ReportaProblem/default.htm*.) Since the inception of the MedWatch program, launched in July 1993 by then FDA Commissioner David Kessler, the program has been promoting and facilitating voluntary reporting by both the general public and health care professionals (Ref. 1). FDA has further encouraged voluntary reporting by requiring inclusion of the MedWatch toll-free telephone number or the MedWatch Internet address on all outpatient drug prescriptions dispensed, as mandated by section 17 of the Best Pharmaceuticals for Children Act (Pub. L. 107–109).

On March 25, 2008, section 906 of the FDA Amendments Act amended section 502(n) of the FD&C Act and mandated that published direct-to-consumer advertisements for prescription drugs include the following statement printed in conspicuous text (this includes vaccine products): ''You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *http://www.fda.gov/medwatch*, or call 1–(800) FDA–1088.'' Most private vendors of consumer medication information, the drug product-specific instructions dispensed to consumers at outpatient pharmacies, remind patients to report ''side effects'' to FDA and provide contact information to permit reporting via the MedWatch process and FDA Form 3500.

Currently, the non-health care professional public may submit voluntary reports using FDA Form 3500 (*http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053074.htm*). This reporting form was created 20 years ago and modeled after an earlier version of the Agency's reporting form for health care professionals. FDA Form 3500 is provided in paper and electronic formats (HTML version at *http://www.fda.gov/medwatch/report.htm* and fillable pdf version at *http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf*), and is used to report to the Agency about serious adverse events, product problems, product use errors, and therapeutic failure (therapeutic inequivalence). Reporting is supported for all FDA-regulated human medical care products, including drugs, biologicals, medical devices, special nutritional products, dietary supplements, cosmetics, and nonprescription (OTC) human drug products marketed without an approved application.

Qualitative assessment by social scientists, and comments and feedback from the public, have recognized that FDA Form 3500 is written and formatted at a literacy/comprehensibility level that far exceeds

the level recommended for the general public by health literacy experts and does not conform to recommendations in the Plain Writing Act of 2010 (*http://www.gpo.gov/fdsys/pkg/PLAW–111publ274/pdf/PLAW–111publ274.pdf).*

The proposed consumer version of the voluntary FDA Form 3500 will request no new data from the voluntary reporter not already included in the existing FDA Form 3500 that is currently used for reporting from both health care professionals and consumers (patients). Certain existing fields not considered essential data for the consumer report but present on the standard (*i.e.,* health care professional) version of FDA Form 3500 have been eliminated to facilitate and expedite consumer submissions and reduce reporting burden. The formatting and plain language used are compatible with the intent of the Plain Writing Act and is expected to provide non-health care professionals with a second option to the existing FDA Form 3500 that will reduce the burden of reporting by facilitating their understanding of the requested data and further clarify the voluntary reporting process.

The proposed consumer version of FDA Form 3500 evolved from several iterations of draft versions, with input from human factors experts, from other regulatory agencies and with extensive input from consumer advocacy groups and the general public. The Agency recognizes that many consumer reporters have a preference for accessing a copy of the voluntary reporting form on the Internet or submitting to FDA using an electronic version of the form. The Agency currently supports voluntary reporting with the forms submitted by mail, by FAX, by telephone via the toll free 800 number and online at *http://www.fda.gov/medwatch/report.htm.* It is the Agency's expectation that an approved consumer version of the voluntary form will be provided for consumer use by these same channels.

In the **Federal Register** of September 9, 2011 (76 FR 55919), FDA published a 60-day notice requesting public comment on the proposed collection of information. Comments were received from seven individuals and organizations.

VI. Response to Comments

1. 3500 Form

(Comment 1) One comment observed that it may be difficult for FDA to identify the pregnancy status of the person experiencing the reported adverse event and suggested that the Agency add a separate field for documenting pregnancy status.

(Response) FDA agrees that documenting pregnancy status is important; however, FDA does not plan to add an additional checkbox for pregnancy to the forms at this time. In 2005, FDA proposed adding checkboxes for both ''Product Used During Pregnancy'' and ''Product Used During Breast Feeding'' to section B.5 of both forms. FDA received comments expressing concern that these new data fields introduced divergence from International Council on Harmonisation standards and appeared to duplicate information that is usually provided in the narrative section and in coded adverse event terms. The pregnancy status data can also be captured in field B7 as ''Other Relevant History''. FDA agreed with the comments and did not include these checkboxes with the 2005 revisions; FDA believes these reasons are still valid.

(Comment 2) One comment encouraged the FDA to use the voluntary consumer version of the form to allow for electronic filing of reports and to continue to promote the reporting process to the public, whether by the traditional paper-based route or electronically.

(Response) FDA agrees with the comment and expects to support both the promotion of the use of the new consumer version of the voluntary form and to explore methods of facilitating reporting and reducing reporter burden by using online and other electronic means of report submission.

(Comment 3) One comment supported the plan to deploy a consumer version of the voluntary form and suggested that its use also be promoted to health care providers for their use. The comment also encouraged the Agency to expedite a process for converting the paper-based reporting process to allow for electronic submission of voluntary reports using the consumer version of the form.

(Response) FDA agrees that support of electronic submissions of voluntary reports should be supported and facilitated. The new form was designed as a consumer friendly option for use by non-health care professionals. The standard FDA Form 3500 will continue to be the primary form offered to health care professionals. FDA encourages the continued use of FDA Form 3500 by health care professionals; however, if a health care professional chooses to submit a report using the consumer form, it will be accepted by FDA.

(Comment 4) One comment stated that implementing a consumer friendly version of FDA Form 3500 would not ''serve any value'' and suggested that instead a more comprehensible form be created that would be used by health care professionals and consumers.

(Response) The Agency disagrees. The current FDA Form 3500 is widely known, well accepted, and used by the range of health care professionals. Assessment of, and feedback from, consumers has demonstrated the demand and need for a modified form that would serve those non-health care professional reporters, using both literacy-appropriate language and formatting that will serve consumers but not be optimal for health care professional reporting.

(Comment 5) A comment suggested that for the proposed change to field E4 from ''Other'' to ''Unique Identifier'' that the term used be ''UDI#''.

(Response) FDA agrees with this comment.

(Comment 6) One comment supported the development of a consumer friendly version of the voluntary form but observed that with the anticipated increase in the number of consumer-initiated reports that the Agency consider a process for ''broader sharing with industry sponsors of adverse event reports made directly to FDA.''

(Response) FDA agrees that adverse event report data should be more readily available to the public (which includes industry). The current mechanisms that FDA has to share reports with industry are the MedWatch to Manufacturer Program and through requests to Freedom of Information. In addition, as part of Phase II of the FDA Transparency Initiative, FDA is planning to provide the public with online access (in a searchable format) to public information from adverse event reports submitted to FDA.

2. 3500A Form

(Comment 7) One comment asked that no changes be made to the FDA Form 3500A at the present time due to consideration of the costs and expenditure of resources incurred by mandatory reporters who are often using electronic systems to do their required reporting to FDA. In addition, the comment noted that there are several proposed or not yet finalized rules that might further impact the content of the mandatory FDA Form 3500. A comment stated that they would ask for a 12-month implementation time to allow for design, testing, and validation of any software changes necessary.

(Response) The Agency has considered the impact of implementing changes to FDA Form 3500A and the need for mandatory reporters to change their electronic systems to comply with the proposed changes. FDA will allow

for sufficient time for design, testing, and validation of any software changes as a result of any new data requirements that may follow from new requirements based on final rules and regulations.

(Comment 8) One comment stated that for mandatory reporters the estimate of burden has been underestimated and fails to take into consideration the effort by firms to collect facts, prepare investigations, and evaluate the data.

(Response) The Agency disagrees that the estimate for the average time to complete a given report is low. This estimate is intended not to represent the totality of the effort for completing the postmarket drug and device safety surveillance process mandated by law, rule, and regulation for application holders but a fair estimate of data collection, organization, entry, and submission time for a given ''average'' report.

(Comment 9) A comment suggested that for the proposed change to field D4 from ''Other'' to ''Unique Identifier'' that the term used be ''UDI#''.

(Response) FDA agrees with this comment. We recommend changing this to UDI#.

(Comment 10) A comment disagreed with requesting an email address from the reporter in field E1, and a second comment expressed similar reservations but suggested that, if used, the initial reporter understand that this information is optional.

(Response) FDA recognizes that an email address is one of several elements in the contact information that may assist FDA and others in effective postmarket safety surveillance and followup inquiries. The reporter is not compelled to complete the information in this field in order for the report to be considered complete and registered in the appropriate database. A statement that this information is optional will be made clear in the instructions for completing the form.

(Comment 11) A comment disagreed with the proposed change in the Section H heading from ''Device Manufacturers Only'' to ''Manufacturers Only''.

(Response) FDA agrees that this title should not be changed. Section H should be titled ''Device Manufacturers Only'' as it currently appears.

(Comment 12) Two comments recommended the addition of a new checkbox field in Section/field H2 named ''Final report'' that would be used to ''reflect the best efforts of the manufacturer to retrieve and analyze information pertaining to the reported event''.

(Response) FDA disagrees that ''Final report'' should be added to Section H2. This information can be added as part of the text narrative in Section H10.

(Comment 13) Two comments disagreed with the removal of field H1's ''Other'' checkbox and stated that there are rare examples of events that do not meet the regulatory definition of death, serious injury, or malfunction but are considered by the mandatory reporting entity to be necessary and required reports. One comment suggested that if the checkbox is removed, that specific instruction be provided for handling reports that would have been compatible with an ''Other'' designation.

(Response) FDA disagrees. FDA recommends removal of the ''Other'' checkbox. In lieu of the checkbox, FDA proposes that rare events that fit the definition of ''Other significant adverse device experiences'' as specified in FD&C Act section 519(a)(3) can be submitted to the FDA using the mailing address identified in 21 CFR 803.12(a).

(Comment 14) One comment suggested changing the title of field B4 from ''Date of This Report'' to ''Date of First Contact With Initial Reporter''.

(Response) FDA disagrees. On August 21, 2009, FDA published a proposed rule (74 FR 42203) to amend part 803 to require manufacturers, importers, and user facilities to submit medical device reports to the Agency in an electronic format (i.e., the 2009 proposed rule). Section II(4)(D)(2) of the 2009 proposed rule specified that in the final rule, FDA specifically proposed to change §§ 803.32(b)(4), 803.42(b)(4), and 803.52(b)(4) from ''date of report by the initial reporter'' to ''date of this report''. Further it states, ''This change would make part 803 consistent with the way that other FDA Centers interpret FDA Form 3500A, Block B4 and how Block B4 appears on FDA Form 3500A.''

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA Center FDA Form (21 CFR Section)	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research:					
Form 3500	28,952	1	28,952	0.60 (36 minutes)	17,371
Form 3500A (§§ 310.305, 314.80, 314.98, and 600.80).	599	96	57,504	1.10.	
Center for Devices and Radiological Health:					
Form 3500	4,585	1	4,585	0.60 (36 minutes)	2,751
Form 3500A (§ 803)	1,485	225	334,125	1.10 (66 minutes).	367,538
Center for Food Safety and Applied Nutrition:					
Form 3500	297	1	297	0.6 (36 minutes).	178
Form 3500A	1,039	1	1,039	1.10 (66 minutes).	1,143
Total					452,234

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

VII. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Kessler, D.A., ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* 269: 2765–2768, 1993.

Dated: December 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–31341 Filed 12–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0858]

Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled ''Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys.''

DATES: Submit either electronic or written comments on the collection of information by February 6, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, II, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Experimental Study on Comparing Data Obtained From Landline Telephone and Cell Phone Surveys—(OMB Control Number 0910–NEW)

I. Background

Since the early 1980s, the Center for Food Safety and Applied Nutrition at FDA has been commissioning several waves of two national consumer surveys, the Food Safety Survey (FSS) and the Health and Diet Survey (HDS), to gather data on consumer knowledge, perceptions, and behaviors regarding food safety and nutrition. The purposes of the surveys are three-fold: (1) To generate nationally representative estimates of knowledge, perception, and practice of interest at a given point in time; (2) to track trends of the estimates over time; and (3) to understand the relationships among knowledge, perceptions, and practices regarding food safety and nutrition and how these relate to demographic characteristics.

Traditionally, all waves of the surveys have been administered via landline telephones and have used the random digit dialing (RDD) technique to recruit national samples of adults (18 years old or above) from households with landline telephone numbers. A noticeable phenomenon that has appeared in our recent surveys is a precipitous decline of younger respondents in completed interviews. For example, the proportion of respondents in the 18 to 29 age group for the FSS has dropped from 17 percent in 2001 to 11 percent in 2006 to only 4 percent in 2010; the corresponding proportion for the HDS has gone from 14 percent in 2002, to 15 percent in 2004, to only 6 percent in 2008.

One possible reason for the decline is the rapid adoption of cell phones in recent years. During the second half of 2010, 28 percent of American adults lived in households with only wireless service (''wireless-only households'' or ''cell-phone only households''), compared to 15 percent in the second half of 2007 and 5 percent in the second half of 2004 (Ref. 1). During the second half of 2010, 17 percent of adults lived in households that received all or almost all calls on cell phones despite having a landline phone (''wireless-mostly households'' or ''cell-phone mostly households''), an increase of 3 percentage points from the first half of 2008 (Ref. 1). Thus, the number of adults reachable by landline phone calls has decreased in recent years. The rate of cell phone adoption, however, has been uneven among adults with different demographic characteristics. In 2010, adults living in wireless-only households were more likely to be 18 to 34 year olds, living in poorer households, without a college or higher educational degree, or Hispanics or Latinos (Ref. 1). Meanwhile, adults who live in landline households differ from those who live in wireless-only households as well those in wireless-mostly households (Ref. 2), and the demographic characteristics of adults living in wireless-mostly households are much less diverse than that of adults living in wireless-only households (Ref. 1).

The under-representation of wireless-only or wireless-mostly adults, especially those in younger age groups, in landline surveys can affect national estimates of the prevalence of certain